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Ms. Wendy A. McCombie
Lewis & Harrison Consultants
Agent for Bio-Tek Industries, Inc.
122 C Street, N.W., Suite 740
Washington, D.C. 20001

Dear Ms. McCombie:

Subject: Addition of Language Required by BCP RED Document
and Addition of New Organism Claims
Tek-Trol Disinfectant Cleaner Concentrate
EPA Registration Number 11725-7
Amended Application Dated October 7, 1997

We have completed a review of the efficacy data, submitted to support additional label claims for the complete inactivation of Porcine Reproduction and Respiratory Syndrome Virus (PRRSV) and conclude the following.

1. The results of the test (MRID No. 444038-02) demonstrate that the subject product "Tek-Trol Disinfectant-Cleaner-Concentrate" when used as directed completely inactivated the subject product PRRSV. Therefore, the claim to "disinfect against Porcine Reproduction and Respiratory Syndrome Virus, Strain ISU-P, ATTC #VR-2402" in accordance with the specific label directions is acceptable.
2. The results of the test (MRID No. 444038-01) demonstrate that Tek-Trol Disinfectant completely killed Vancomycin resistant Enterococcus faecalis and Methicillin resistant Staphylococcus aureus. Therefore, the claim "Disinfectant passes the AOAC use-dilution test against Vancomycin resistant Enterococcus faecalis and Staphylococcus aureus" is acceptable.

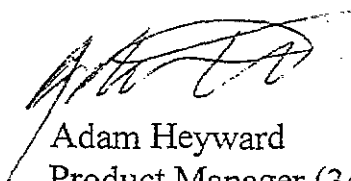
		CONCURRENCES					
SYMBOL	11725-7						
SURNAME	W. A. McCombie						
DATE	4/10/98						

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The amended labeling of the date referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. A stamped copy is enclosed for your records. One copy of the finished labeling must be submitted prior to releasing the product for shipment.

For detailed consideration, please refer to the attached EPA RASSB review dated April 1, 1998. If you have any questions, please contact LaVerne Dobbins at (703) 308-6378.

Sincerely,



Adam Heyward
Product Manager (34)
Regulatory Management Branch II
Antimicrobials Division (7510W)

Enclosure:
Stamped label
RASSB Efficacy Review

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**TEK-TROL
DISINFECTANT - CLEANER CONCENTRATE**

FOR USE IN POULTRY, SWINE, EQUINE, VEAL, AVIAN, VETERINARY,
RATITE, CALVING, AND ANIMAL CARE FACILITIES

STAPHYLOCIDAL • PSEUDOMONACIDAL • SALMONELLACIDAL
ASPERGILLOCIDAL • TUBERCULOCIDAL • VIRUCIDAL*
FUNGICIDAL • PARVOCIDAL • MILDEWCIDAL • DEODORANT

ACTIVE INGREDIENTS:

ortho-Phenylphenol	12.0%
ortho-Benzyl-para-chlorophenol	10.0%
para-tertiary-Amylphenol	4.0%

INERT INGREDIENTS:

	74.0%
TOTAL:	100.0%

EPA REG. NO. 11725-7

EPA EST. NO. 11725-GA-1

PROVEN EFFECTIVE IN 10% BLOOD SERUM AND 1000 PPM WATER HARDNESS

**KEEP OUT OF REACH OF CHILDREN
DANGER**

**PRECAUTIONARY STATEMENTS:
Hazard to Humans and Domestic Animals**

Danger. Corrosive. Causes irreversible eye damage and skin burns. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield, protective clothing, and chemical-resistant rubber gloves when handling. Harmful if swallowed. Wash thoroughly with soap and water after handling and before eating, drinking or using tobacco. Remove contaminated clothing and wash before reuse.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Applicators and other handlers must wear:

- long sleeve shirt and long pants
- socks plus shoes
- chemical-resistant gloves

In addition, for applicators and other handlers exposed to fog during fogging applications, and until fog has dissipated and the enclosed area has been thoroughly ventilated, must wear:

- a full face respirator with a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G)

User Safety Recommendations

Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet. Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

STATEMENT OF PRACTICAL TREATMENT

IF ON SKIN: Wash with plenty of soap and water. Get medical attention.

IF IN EYES: Hold eyelids open and flush eyes with a steady, gentle stream of water for 15 minutes. Get medical attention.

IF SWALLOWED: Call a doctor or get medical attention. Do not induce vomiting or give anything by mouth to an unconscious person. Drink promptly a large quantity of milk, egg whites, gelatin solution, or, if these are not available, large quantities of water. Avoid alcohol.

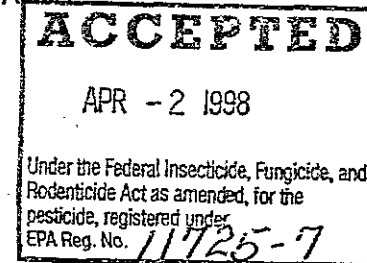
NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression and convulsion may be needed.

•CONDUCTIVE•

TEK-TROL has been tested by Hood Patterson-Dewar, Electrical Testing Engineers, for its effect on conductive flooring. The method used conforms to the specifications known as NFPA Standard No. 56A, published by the National Fire Protection Association, Second Edition, 1987. TEK-TROL meets the requirement of NFPA 56A

Manufactured by:

BIO-TEK INDUSTRIES, Inc.
1330 West Marietta Street, N.W., Atlanta, GA 30338, USA
Telephone (404) 799-2050 Telex: 67-2344
FAX: (404) 799-2058



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DESCRIPTION

TEK-TROL is a synthetic detergent with broad spectrum kill of gram positive and gram negative microorganisms, provides effective cleaning and disinfecting in one operation, non-flammable and non-volatile in use dilutions, excellent solubility, dilutes in hot, cold, soft or hard water of up to 1000 ppm water hardness.

The TEK-TROL high foaming detergent system has been especially formulated to provide heavy duty cleaning, wetting and penetration of soils and organic matter and easy rinsing of surfaces. Excellent clinging foam is obtained at 1/2 oz. per gallon of water (1:256) to provide prolonged contact time.

TEK-TROL, at 1/2 oz. per gallon of water (1:256) provides residual control of odor causing bacteria in the presence of moisture.

TEK-TROL is recommended for use when used as directed on ceramic and glazed tile surfaces, stainless steel, aluminum, chrome, galvanized metal, glass, and other hard non-porous environmental surfaces such as treated wood, polyethylene, polypropylene, PVC (polyvinyl chloride), polystyrene, vinyl, fiberglass, viton, ethylene propylene, nitrile, acrylic, and polyurethane.

TEK-TROL at 1/2 oz. per gallon of water (1:256) is suited for disinfecting and cleaning hard nonporous environmental surfaces in all areas of: swine producing facilities, including farrowing and nursery units, finishing floors, grow barns, confinement units, and transport vehicles; poultry, turkey, duck, ratite, and avian rearing facilities, including grow-out breeder barns, laying operations, and hatcheries, including hatchers and setters, evaporative coolers, fogging systems, humidifying systems, live haul equipment, chick busses, transfer trucks, coop washing, chick boxes, foot pans, trays, feed bins and buggies; calving facilities, including calf hutches and pens, freshening pens, and birthing pens; equine facilities including stables, stalls, breeding and foaling sheds and transport vehicles; hospitals, medical research centers, health care facilities, schools, animal care facilities and research centers, laboratories, veterinary clinics, zoos, and kennels. TEK-TROL can also be used as a wall and floor cleaner in poultry and meat processing plants, meat packing plants, frozen food and canning operations.

TEK-TROL is recommended for use in fogging (wet misting) operations as an adjunct sanitizer of room surfaces either preceding or following regular cleaning and disinfecting procedures. Use at a dilution of 1/2 oz. per gallon (1:256). Check with a Bio-Tek representative to determine effective fogging schedule for particular use sites. Leave the room when fogging. In well ventilated areas, such as hatcheries, only 10 to 15 minutes is necessary before reentering. If used in a poorly ventilated area, allow at least 2 hours, or air thoroughly, before reentry. Before fogging in food processing areas, all food and food packaging items must be removed or carefully protected. To thoroughly clean and disinfect room surfaces, before or after fogging, scrub with TEK-TROL at 1/2 oz. per gallon (1:256). Disinfected food contact surfaces must be rinsed with potable water prior to reuse.

Toxicity tests required by the U.S. Environmental Protection Agency for TEK-TROL DISINFECTANT-CLEANER have been done in conformity with the EPA Good Laboratory Practice Regulations.

Proven effective as a disinfectant by the following tests: A.O.A.C. (use dilution test method) in conformance with the 14th Edition 1984. All dilutions at 1:256. The following organisms tested at 1000 ppm water hardness (as calcium carbonate) and 10% horse serum (as organic soil):

- Alcaligenes faecalis, Strain# 838
- Alcaligenes faecalis, Georgia Strain
- Aspergillus fumigatus, ATCC# 6285
- Beta streptococcus, ATCC#19615
- Bordetella bronchiseptica, ATCC# 10580
- Candida albicans, ATCC# 18804
- A.O.A.C. Fungicidal Test
- Enterobacter aerogenes, ATCC# 13048
- Enterococci Group D Species
- Vancomycin-Resistant Enterococcus faecalis (VRE), ATCC #51299
- Escherichia coli, ATCC# 11229
- Haemophilus parasuis, ATCC# 19417
- Klebsiella pneumoniae, ATCC# 4352
- Microsporium canis, ATCC# 42872
- A.O.A.C. Fungicidal Test
- Microsporium gypseum, ATCC# 52027
- A.O.A.C. Fungicidal Test

- Rhodococcus equi, ATCC#6939
- Salmonella arizonae PD 36
- Salmonella arizonae #7:1, 7,8
- Salmonella choleraesuis, ATCC# 10708
- Salmonella choleraesuis, Kunzendorf Strain
- Salmonella enteritidis, ATCC# 13076
- Salmonella gallinarum, ATCC# 9184
- Salmonella pullorum, ATCC# 19945
- Salmonella schottmuelleri, ATCC# 8749
- Salmonella typhimurium, ATCC# 13311
- Shigella sonnei ATCC# 25931
- Methicillin-Resistant Staphylococcus aureus (MRSA), ATCC # 33591
- Staphylococcus aureus, ATCC# 6538
- Staphylococcus epidermis
- Staphylococcus hyicus
- Streptococcus equi, ATCC#39506

ACCEPTED

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Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 11725-7

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Mycobacterium bovis (BCG)
 A.O.A.C. Tuberculoicidal Test
 Mycoplasma synoviae
 Mycoplasma gallisepticum
 Mycoplasma hyopneumoniae, ATCC# 25934
 Pasteurella anatipestifer
 Pasteurella multocida, ATCC# 6529
 (fowl cholera)
 Proteus vulgaris, ATCC# 13315
 Pseudomonas aeruginosa, ATCC# 15442

Streptococcus pyogenes, ATCC# 9342
 Streptococcus pyogenes, ATCC# 19615
 Streptococcus suis, Type II
 Taylorella equigenitalis (C.E.M.)
 Kentucky Strain 3056
 Trichophyton equinarum, ATCC# 64916
 A.O.A.C. Fungicidal Test
 Trichophyton mentagrophytes, ATCC# 9533
 A.O.A.C. Fungicidal Test

*The following Viruses tested in accordance with U.S. Environmental Protection Agency Pesticide Assessment Guidelines on hard, nonporous inanimate environmental surfaces. Tested at 1000 ppm water hardness (as calcium carbonate) and 10% serum (as organic soil):

Avian adenovirus
 Avian infectious bronchitis virus
 Avian influenza virus
 Avian Laryngotracheitis
 Avian reovirus
 Avian rotavirus ATCC# VR-1
 Canine adenovirus ATCC# VR-800
 Canine coronavirus ATCC# VR-809
 Canine parvovirus, Strain CPV.MLV (Cornell)
 Duck enteritis virus (D.V.E.)
 Equine arteritis, ATCC#VR-796 (Equine viral arteritis)
 Equine herpes virus, ATCC# VR-700 (Equine rhinopneumonitis)
 Equine Rotavirus

Feline calicivirus, ATCC# VR-782
 Feline rhinotracheitis ATCC# VR-636
 Herpes Simplex Type 1
 HIV-1 (AIDS virus)
 Influenza A-2/Hong Kong virus, ATCC# VR-544
 Mouse hepatitis virus, Strain MHV-A59, ATCC # VR-764
 Newcastle disease virus
 Parainfluenza virus, Type I, Sendai Strain ATCC# VR-105
 Porcine Reproduction and Respiratory Syndrome Virus,
 Strain ISU-P ATCC #VR-2402
 Porcine rotavirus, ATCC#VR-893
 Pseudorabies virus, Aujeszky Strain, ATCC# VR-135
 Transmissible gastroenteritis virus,
 Purdue Strains, ATCC# VR-763

Hard Surface Mildewicidal Test Method: CSMA method 23 at 1000 ppm water hardness (as calcium carbonate) and 10% horse serum (as organic soil):

Aspergillus niger ATCC# 6275
 (black mold)

Penicillium variable NRRL# 3765
 (Green mold)

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 Under the Federal Insecticide, Fungicide, and
 Rodenticide Act as amended, for the
 pesticide, registered under
 EPA Reg. No. 11725-7

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. Following application as a low pressure or high pressure spray, do not enter or allow others to enter the treated area until sprays have dried. Thoroughly ventilate entire closed area after fogging applications. Do not enter, allow other persons to enter, house livestock, or use equipment in the treated area until ventilation is complete and any liquid has been absorbed, set, or dried. For entry into fogged areas before ventilation is complete and the fog has completely dissipated, all persons must wear the personal protective equipment, including a full-face respirator, required in the precautionary statement section of this labeling for applicators and other handlers.

HOSPITAL USE DIRECTIONS:

1. To clean, disinfect, and deodorize walls and other hard non-porous environmental surfaces, use 1/2 oz. of TEK-TROL per gallon of water (1:256). Apply with cloth, sponge, mop, mechanical spray device or foaming apparatus, making sure all surfaces are wetted thoroughly. Allow surface to remain wet for 10 minutes. For heavily soiled areas a preliminary cleaning is required, remove gross soil and proceed per above.
2. After treatment, rinse surfaces with potable water.
3. TEK-TROL is an effective tuberculocide against *Mycobacterium bovis* in 10 minutes at 20° C when used on hard non-porous inanimate environmental surfaces. Follow above directions, including removal of gross filth or heavy soil prior to application of TEK-TROL.
4. KILLS HIV ON PRECLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS in health care settings or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of human immunodeficiency virus Type 1 (HIV-1) (associated with AIDS).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV OF SURFACES/ OBJECTS SOILED WITH BLOOD/BODY FLUIDS:

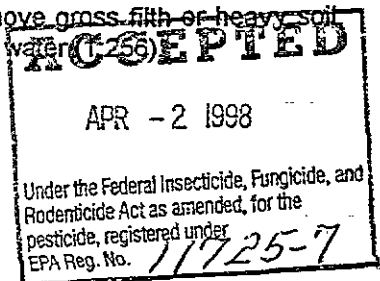
- PERSONAL PROTECTION: When handling items soiled with blood or body fluids, use protective equipment such as disposable rubber gloves, gowns, masks or eye coverings.
- CLEANING PROCEDURE: Blood or body fluids must be thoroughly cleaned from surfaces and objects before application of this disinfectant.
- CONTACT TIME: To kill HIV-1 (AIDS virus) a contact time of 10 minutes at room temperature must be allowed.
- DISPOSAL OF INFECTIOUS MATERIALS: Blood and other body fluids should be autoclaved and disposed of according to local regulations for infectious waste disposal.

HATCHING EGG SANITIZER:

TEK-TROL is recommended for use as a Hatching Egg Sanitizer, with best results being achieved in water temperatures ranging from 78°F to 110°F. The recommended dilution is 1/2 oz. per gallon of water (1:256), and may be applied through automatic washing systems, immersion tanks, foaming apparatus, low pressure sprayers, and fogging (wet misting) systems.

GENERAL USE DIRECTIONS:

1. To clean, disinfect and deodorize walls, floors, tables, drinking fountains, sinks, refrigerators, stoves, restroom fixtures and garbage cans: Remove gross filth and heavy soil with a preliminary cleaning step prior to application of TEK-TROL. Apply solution of 1/2 oz. of TEK-TROL per gallon of water (1:256) with a sponge, mop, mechanical spray device or foaming apparatus making sure that all surfaces are wetted thoroughly. Allow surface to remain wet for 10 minutes. Air dry.
2. To clean and disinfect such articles as food and water bowls, non-porous bird toys, non-porous perches, combs, brushes, razors, scissors, and rubber goods: all articles must be thoroughly cleaned to remove excess debris, rinsed and rough dried, including the hollows and lumens, before immersion in solution. Soak for 10 minutes in a solution containing 1/2 oz. TEK-TROL per gallon of water (1:256). Rinse food and water bowls prior to reuse.
3. To disinfect fabrics such as sheets, linens, aprons and uniforms: First rinse to remove gross filth or heavy soil then soak for 10 minutes in a solution containing 1/2 oz. of TEK-TROL per gallon of water (1:256).



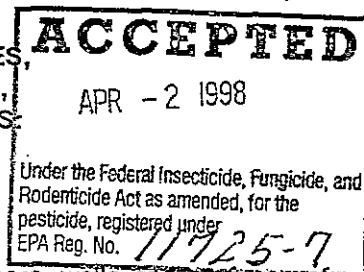
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4. To clean gross filth or heavy soil on environmental surfaces prior to disinfection, use 1/2 oz. of TEK-TROL per gallon of water (1:256).
5. Dilution ratios: use 1/2 oz. (15cc) of TEK-TROL per gallon of water (1:256) [use 1/16 oz (2cc) of TEK TROL per 16 oz. of water (1:256); 1/8 oz (4cc) TEK TROL per 32 oz. of water (1:256); 3/16 oz. (6cc) of TEK-TROL per 48 oz of water (1:256)].

BIO-TEK INDUSTRIES, INC., recommends the use of the BIO-TEK proportioner to provide the automatic method to obtain the 1/2 oz. per gallon solution (1:256).

DIRECTIONS FOR USE IN POULTRY HOUSES, RATITE RANCHES, AVIARIES, FARM PREMISES, SWINE PRODUCING FACILITIES, EQUINE FACILITIES VEAL BARNs, AND CALVING OPERATIONS:



DO NOT USE IN MILKING STALLS, MILKING PARLORS, OR MILK HOUSES.

1. Remove all animals, poultry and feed from the premises.
2. Remove all trucks, coops, crates, water troughs and feed racks.
3. Remove all gross soil, litter, manure, droppings from animals and poultry from floors, walls and surfaces of barns, pens, stalls, chutes and other facilities and fixtures occupied or traversed by animals and poultry.
4. Thoroughly clean and saturate all surfaces with a solution of 1/2 oz. of TEK-TROL per gallon of water (1:256). Use high pressure sprayer or apply layer of foam with BIO-TEK foaming apparatus.
5. Allow to remain in contact for at least ten minutes.
6. Immerse halters, ropes and other types of equipment used in handling and restraining animals, forks, shovels, scrapers used for removing litter and manure, in a solution of TEK-TROL at 1/2 oz. per gallon of water (1:256). Allow to remain in contact for 10 minutes.
7. Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains, waterers, and mangers with a solution of TEK-TROL at 1/2 oz. per gallon of water (1:256). Rinse with potable water before reuse.
8. Ventilate buildings, coops and other closed spaces. Do not house poultry or livestock or employ equipment until treatment has been absorbed, set or dried.

BIRD CAGES:

REMOVE BIRDS AND FOOD/WATER BOWLS FROM CAGE

To clean, disinfect and deodorize bird cages and cage floors, remove gross filth and bird droppings with a preliminary cleaning step prior to application of TEK-TROL. To mix solution of TEK-TROL using calibrated dropper, mix 2 cc of TEK-TROL to 16 oz. of water in the TEK-TROL spray bottle or any other clean spray bottle. For larger solutions, mix 1/2 oz. (15 cc) per gallon of water (1:256). Spray or wipe making sure all surfaces are wetted thoroughly. Allow surface to remain wet for 10 minutes. Air dry. Return birds to cage.

STORAGE AND DISPOSAL

Pesticide Disposal – Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

Do not contaminate water, food, or feed by storage or disposal.

Container Disposal – Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

NET CONTENTS* _____ U.S. GALLONS

***(AS PER PR NOTICE 95-1, THE FOLLOWING EFFLUENT DISCHARGE LANGUAGE APPEARS ONLY ON CONTAINERS WITH A NET CONTENT GREATER THAN OR EQUAL TO 5 GALLONS):**

ENVIRONMENTAL HAZARDS

[Do not discharge effluent containing this product into lakes, ponds, streams, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the

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permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.]

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Under the Federal Insecticide, Fungicide, and
Rodenticide Act as amended, for the
pesticide, registered under
EPA Reg. No. 11725-7